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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
SPIEGLER, A	
ART UNIT	**PAPER NUMBER**
1656	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/590,583	Applicant(s) FRUDAKIS ET AL.	
	Examiner Alexander H. Spiegler	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *8-10,17-22 and 31* is/are objected to.

8)☒ Claim(s) *1-7,11-16,23-30 and 32-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 8-10, 17-22 and 31 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 8-10, 17-22 and 31 have not been further treated on the merits.

Election/Restrictions

2. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented claims 17-22 and 35, 38-39 in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct inventions (polypeptides, polynucleotides, antibodies, antigen-presenting cells) to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species.

3. In addition, each Group detailed below reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid or nucleic acid sequences, the Applicants must further elect a single amino acid or a single nucleic acid sequence (See MPEP 803.04).

4. It is noted that the restriction Groups are set forth as Groups I-XXIII for convenience. However, each restriction Group actually comprises the numbers of Groups which read on each patentably distinct nucleic acid, polypeptide, fusion protein or antibody specificity.

5. In addition, it is noted that claims 12-16, drawn to a fusion protein comprising at least one polypeptide according to claim 1 would be subject to further restriction, as each fusion protein comprising more than one polypeptide would differ in structure and modes of action to such extent as to be considered patentably distinct.

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-7, 16 and 58-60, drawn to an isolated polynucleotide, isolated nucleotide encoding fusion protein and a kit comprising the polynucleotide, classified in class 536, subclass 23.1, and in class 435, subclass 810.

II. Claims 1-3 drawn to an isolated polypeptide, classified in class 530, subclass 300.

III. Claims 12-16, drawn to a fusion protein, classified in class 536, subclass 23.4

IV. Claims 11 and 54-57, drawn to an antibody to a polypeptide and a kit comprising the antibody, classified in class 530, subclass 387.1, and in class 435, subclass 810.

V. Claims 23-28, drawn to a pharmaceutical composition or a vaccine comprising an antigen-presenting cell, classified in class 424, subclass 93.1.

VI. Claims 29-30, drawn to a method for inhibiting the development of cancer comprising administering to a patient an effective amount of antigen-presenting cell, classified in class 424, subclass 93.7.

VII. Claims 32-33, drawn to a method for removing tumor cells from a biological sample, classified in class 435, subclass 375.

VIII. Claim 34, drawn to a method for inhibiting the development of cancer comprising administering to a patient a biological sample, classified in class 424, subclass 577.

IX. Claim 35 (in part), drawn to a method for stimulating and/or expanding T cells, comprising contacting T-cells with a polypeptide, classified in class 435, subclass 377.

If Group IX is elected, claim 35 will be examined to the extent that it reads on the polypeptide.

X. Claim 35 (in part), drawn to a method for stimulating and/or expanding T cells, comprising contacting T-cells with a polynucleotide, classified in class 435, subclass 377.

If Group X is elected, claim 35 will be examined to the extent that it reads on the polynucleotide.

XI. Claim 35 (in part), drawn to a method for stimulating and/or expanding T cells, comprising contacting T-cells with antigen presenting cells, classified in class 435, subclass 377.

If Group XI is elected, claim 35 will be examined to the extent that it reads on the antigen presenting cells.

XII. Claim 36, drawn to an isolated T cell population, classified in class 424, subclass 93.71.

XIII. Claim 37, drawn to a method for inhibiting the development of cancer comprising administering to a patient an effective amount of T cells, classified in class 435, subclass 93.1.

XIV. Claim 38 (in part), drawn to a method for inhibiting the development of cancer comprising incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with a polypeptide and administering to the patient an effective amount of the proliferated T cells, classified in class 435, subclass 93.1.

If Group XIV is elected, claim 38 will be examined to the extent that it reads on the polypeptide.

XV. Claim 38 (in part), drawn to a method for inhibiting the development of cancer comprising incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with a polynucleotide and administering to the patient an effective amount of the proliferated T cells, classified in class 435, subclass 93.1.

If Group XV is elected, claim 38 will be examined to the extent that it reads on the polynucleotide.

XVI. Claim 38 (in part), drawn to a method for inhibiting the development of cancer comprising incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with antigen presenting cells and administering to the patient an effective amount of the proliferated T cells, classified in class 435, subclass 93.1.

If Group XVI is elected, claim 38 will be examined to the extent that it reads on the antigen presenting cells.

XVII. Claim 38 (in part), drawn to a method for inhibiting the development of cancer comprising incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with a polypeptide, cloning at least one proliferated cell and administering to the patient an effective amount of the cloned T cells, classified in class 435, subclass 93.1.

If Group XVII is elected, claim 38 will be examined to the extent that it reads on the polypeptide.

XVIII. Claim 39 (in part), drawn to a method for inhibiting the development of cancer comprising incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with a polynucleotide, cloning at least one proliferated cell and administering to the patient an effective amount of the cloned T cells, classified in class 435, subclass 93.1.

If Group XVIII is elected, claim 39 will be examined to the extent that it reads on the polynucleotide.

XIX. Claim 39 (in part), drawn to a method for inhibiting the development of cancer comprising incubating $CD4^+$ and/or $CD8^+$ T cells isolated from a patient with antigen presenting cells, cloning at least one proliferated cell and administering to the patient an effective amount of the cloned T cells, classified in class 435, subclass 93.1.

If Group XIX is elected, claim 39 will be examined to the extent that it reads on the antigen presenting cells.

XX. Claims 40-43, drawn to a method for determining the presence or absence of cancer in a patient, comprising contacting a biological sample obtained from a

patient with a binding agent, the binding agent being an antibody, classified in class 435, subclass 7.1.

XXI. Claims 44-47, drawn to a method for monitoring the progression of a cancer in a patient, comprising contacting a biological sample obtained from a patient with a binding agent at different time points, the binding agent being an antibody, classified in class 435, subclass 7.1.

XXII. Claims 48-50, drawn to a method for determining the presence or absence of cancer n a patient, comprising contacting a biological sample obtained from a patient with an oligonucleotide, class 435, subclass 6.

XXIII. Claims 51-53, drawn to a method for monitoring the progression of a cancer in a patient, comprising contacting a biological sample obtained from a patient with an oligonucleotide at different time points, class 435, subclass 6.

7. Inventions I and (II and III) are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups II and III, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Groups II and III to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and (II and III) supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from

being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

8. Inventions I and IV are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Group IV are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

9. Inventions I and V are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Group V are drawn to a pharmaceutical composition or a vaccine comprising an antigen-presenting cell. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention V would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

10. Inventions I and (VI-IX, XI, XIII-XIV, XVI-XVII, XIX-XXI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotide of Group I is not required for the methods of Groups VI-IX, XI, XIII-XIV, XVI-XVII, XIX-XXI.

11. Inventions I and (X, XV, XVIII, XXII-XXIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I could be used for an entirely different purpose such as in making the polypeptide of Group II, rather than in the methods of Groups X, XV, XVIII, XXII-XXIII.

12. Inventions I and XII are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claim of Group XII is drawn to isolated T cells. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention XII would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

13. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a polypeptide and a fusion polypeptide, and these are two different entities with different functions and different modes of operation.

14. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in the method of Group IX, rather than for the production of antibodies of Group IV.

15. Inventions II and V are separate and distinct, as the claims of Invention II are drawn to polypeptides, while the claims of Group V are drawn to a pharmaceutical composition or a vaccine comprising an antigen-presenting cell. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention V would require searching in areas unrelated to polypeptides, and as such, would require an undue burden on the examiner if not restricted.

16. Inventions II and (VI-VIII, X-XI, XIII, XV-XVI, XVIII-XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptide of Group II is not required for the methods of Groups VI-VIII, X-XI, XIII, XV-XVI, XVIII-XXIII.

17. Inventions II and (IX, XIV, XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in making the antibodies of Group IV, rather than in the methods of Groups IX, XIV and XVII.

18. Inventions II and XII are separate and distinct, as the claims of Invention II are drawn to polypeptides, while the claim of Group XII is drawn to isolated T cells. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention

XII would require searching in areas unrelated to polypeptides, and as such, would require an undue burden on the examiner if not restricted.

19. Inventions III and IV are separate and distinct, as the claims of Invention III are drawn to a fusion polypeptide, while the claims of Group IV are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to fusion polypeptides, and as such, would require an undue burden on the examiner if not restricted.

20. Inventions III and V are separate and distinct, as the claims of Invention III are drawn to a fusion polypeptide, while the claims of Group V are drawn to a pharmaceutical composition or a vaccine comprising an antigen-presenting cell. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention V would require searching in areas unrelated to fusion polypeptides, and as such, would require an undue burden on the examiner if not restricted.

21. Inventions III and (VI-XI, XIII-XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the fusion polypeptide of Group III is not required for the methods of Groups VI-XI, XIII-XXIII.

22. Inventions III and XII are separate and distinct, as the claims of Invention III are drawn to a fusion polypeptide, while the claim of Group XII is drawn to isolated T cells. These are differing biochemical entities having differing biochemical properties, structures and effects.

Invention XII would require searching in areas unrelated to fusion polypeptides, and as such, would require an undue burden on the examiner if not restricted.

23. Inventions IV and V are separate and distinct, as the claims of Invention IV are drawn to an antibody, while the claims of Group V are drawn to a pharmaceutical composition or a vaccine comprising an antigen-presenting cell. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention V would require searching in areas unrelated to antibodies, and as such, would require an undue burden on the examiner if not restricted.

24. Inventions IV and (VI-XI, XIII-XIX, XXII-XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibody of Group IV is not required for the methods of Groups VI-XI, XIII-XIX, XXII-XXIII.

25. Inventions IV and (XX-XXI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV could be used for an entirely different purpose such as in detecting the antigen-presenting cells, rather than in the methods of Groups XX-XXI.

26. Inventions IV and XII are separate and distinct, as the claims of Invention IV are drawn to an antibody, while the claim of Group XII is drawn to isolated T cells. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention XII would require searching in areas unrelated to antibodies, and as such, would require an undue burden on the examiner if not restricted.

27. Inventions V and (VI, XI, XVI and XIX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition or vaccine of Group V could be used for an entirely different purpose such as an immunogen, rather than in the methods of Groups VI, XI, XVI and XIX.

28. Inventions V and (VII-X, XIII-XV, XVII-XVIII, XX-XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the pharmaceutical composition or vaccine of Group V is not required for the methods of Groups VII-X, XIII-XV, XVII-XVIII, XX-XXIII.

29. Inventions V and XII are separate and distinct, as the claims of Invention V are drawn to a pharmaceutical composition or a vaccine, while the claim of Group XII is drawn to isolated T cells. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention XII would require searching in areas unrelated to pharmaceutical

compositions or vaccines, and as such, would require an undue burden on the examiner if not restricted.

30. Inventions XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the isolated stimulated T cells can be made using small molecules rather than a method of Group XI.

31. Inventions XII and (VI-X, XIV-XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the isolated T cells of Group XII are not required for the methods of Groups VI-X, XIV-XXIII.

32. Inventions XII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T cells of Group XII could be used for an entirely different purpose such as in the method of Group VII, rather than in the method of Group XIII.

33. Inventions VI-XI, XIII-XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation,

or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

34. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XXIII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

35. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

36. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
August 10, 2001

KENNETH R. HORLICK, Ph.D.
PRIMARY EXAMINER
GROUP 1800
8/13/01